
Guidance for Industry

FOOD LABELING: *TRANS* FATTY ACIDS IN NUTRITION LABELING, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS

SMALL ENTITY COMPLIANCE GUIDE

Comments and suggestions regarding this document may be submitted at any time. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Julie Schrimpf at the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-2373.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

[insert date]

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Additional copies are available from:

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U.S. Department of Health and Human Services

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This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternate approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

On July 11, 2003, the Food and Drug Administration (FDA) published a final rule in the **Federal Register** that amended its regulations on food labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements (68 FR 41434). This rule is effective January 1, 2006.

FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Fairness Act (P.L. 104-121). This guidance document restates in plain language the legal requirements set forth in 21 CFR 101.9 and 101.36 concerning the declaration of *trans* fatty acids in the nutrition label of conventional foods and dietary supplements, respectively.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹This guidance has been prepared by the Division of Nutrition Programs and Labeling, Office of Nutritional Products, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

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II. DISCUSSION

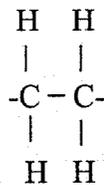
1. What are fatty acids?

Fatty acids are the chemical compounds that make up fats. Fatty acids are chains of carbon atoms with hydrogen atoms attached to the carbon atoms. A "saturated" fatty acid has the maximum possible number of hydrogen atoms attached to every carbon atom. It is therefore said to be "saturated" with hydrogen atoms.

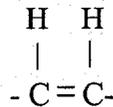
Sometimes a pair of hydrogen atoms in the middle of a chain is missing, creating a gap that leaves two carbon atoms connected by a double bond, rather than a single bond. The missing hydrogen atoms cause the chain to be "unsaturated." A fatty acid that has one double bond is said to be "monounsaturated." Fatty acids having more than one double bond are called "polyunsaturated." Usually, the hydrogen atoms at a double bond are positioned on the same side of the carbon chain. In fact, all fatty acids listed as "monounsaturated" and "polyunsaturated" in nutrition labeling are of this type (i.e., in the "cis" configuration).

The structure of saturated and unsaturated chemical bonds is represented in the diagram below.

Saturated Fatty Acid



Unsaturated Fatty Acid (cis fatty acid)



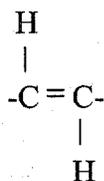
2. What are *trans* fatty acids?

Trans fatty acids, also known as *trans* fats, are made during partial hydrogenation of vegetable oils. Hydrogenation is the process by which hydrogen atoms are added to unsaturated sites on fatty acids, thereby, eliminating double bonds. Partial hydrogenation relocates some double bonds and hydrogen atoms end up on different sides of the chain. This type of configuration is called "*trans*" (means "across" in Latin).

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The structure of a *trans* unsaturated chemical bond is represented in the diagram below.

***Trans* Fatty Acid**



3. Why is FDA requiring that *trans* fatty acids be listed in nutrition labeling?

FDA is requiring that *trans* fatty acids be listed in nutrition labeling in response to a petition from the Center for Science in the Public Interest and to published human studies that show that intake of *trans* fatty acids, similar to the intake of saturated fatty acids, increases low density lipoprotein-cholesterol (LDL-C) ("bad cholesterol") in the blood. An elevated LDL-C increases the risk of developing coronary heart disease. Reports published by the Institute of Medicine of the National Academy of Sciences (IOM/NAS) and the Federal government have recommended that Americans limit their intake of *trans* fat and other cholesterol-raising fats while consuming a nutritionally adequate diet. For Americans to follow these recommendations, they must know the amount of *trans* fatty acids in the individual foods that they eat. Therefore, FDA is requiring that this information be provided in nutrition labeling to assist consumers in maintaining healthy dietary practices.

4. Do *trans* fatty acids need to be listed when mono- and polyunsaturated fatty acids are not listed?

Yes. The listing of *trans* fatty acids is mandatory even when mono- and polyunsaturated fatty acids are not listed.

5. How should *trans* fatty acids be listed?

Trans fatty acids should be listed as "*Trans* fat" or "*Trans*" on a separate line under the listing of saturated fat in the nutrition label. *Trans* fat content must be expressed as grams per serving to the nearest 0.5-gram increment below 5 grams and to the nearest gram above 5 grams. If a serving contains less than 0.5 gram, the content, when declared, must be expressed as "0 g."

6. If a serving contains less than 0.5 gram of *trans* fat, when would "0 g" of *trans* fat not have to be declared?

For conventional food products (those food products other than dietary supplements), declaration of "0 g" of *trans* fat is not required for such products that contain less than 0.5 g of total fat in a serving if no claims are made about fat, fatty acid, or cholesterol content. In the absence of these claims, the statement "Not a significant source of *trans* fat" may be placed at the bottom of the

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table of nutrient values in lieu of declaring "0 g" of *trans* fat.

The labeling of dietary supplements is different than the labeling of conventional foods. Certain nutrients in conventional foods, when not present or when present at levels that the agency has determined to be "zero" (see 21 CFR 101.9(c)), must be listed as zero on conventional food labels. However, when those same nutrients are not present in dietary supplements or present in dietary supplements at levels that the agency has determined, for conventional foods, to be "zero," such nutrients must not be listed on dietary supplement labels. Amounts of "0 g" and "Not a significant source..." statements are not allowed in the nutrition labeling of dietary supplements (i.e., Supplement Facts). Consequently, when the amount of *trans* fat in a dietary supplement is less than 0.5 gram per serving, *trans* fat must not be listed on the Supplement Facts panel.

7. What should be listed as the "% DV" for *trans* fat?

FDA recommends that you leave this blank. No percent is shown because there is no Daily Value for *trans* fatty acids

8. Is the footnote "Intake of *trans* fat should be as low as possible" required?

No. A footnote of this type is not required. The IOM/NAS report recommended that "*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Shortly after the issuance of this report, FDA proposed the use of an explanatory footnote, "Intake of *trans* fat should be as low as possible." However, we received very negative comments on the wording of this footnote. As a result, FDA is conducting consumer studies and has issued an advance notice of proposed rulemaking (ANPR) on this issue (68 FR 41507; July 11, 2003). In the ANPR, FDA is soliciting data and information on the effectiveness of various footnotes, including those that address saturated fat and cholesterol in addition to *trans* fatty acids. Consequently, there is no regulation requiring the use of a footnote at this time.

9. Will the content of total fat be changed?

No, because *trans* fat is already included in the amount declared for "Total Fat."

10. Does the final rule change the regulations dealing with nutrient content or health claims?

No. The sections of the November 17, 1999 proposal (64 FR 62746) dealing with nutrient content and health claims are being withdrawn. The agency is asking for comment and data, in an ANPR (referenced above in response to question #8), that could assist the agency in a future rulemaking when considering *trans* fat levels in nutrient content and health claims.

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11. Can *trans* fatty acids be labeled right now?

Yes.

12. When does this rule become effective?

The effective date of this final rule is January 1, 2006. Starting on this date, food labels, including those for certain dietary supplements, must include *trans* fat in nutrition labeling on products being introduced into interstate commerce.